REMARKS

Claims 53-85 are currently pending in the application. Claims 61, 62, 77, and 78 have been amended. Support for the amended claims is found in Table 10 on page 108. The Examiner is respectfully requested to reconsider her rejections in view of the amendments and remarks as set forth herein below.

Claim Rejection-35 USC § 112, first paragraph

Claims 67, 68 and 83-85 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

Independent claims 67 and 83 are drawn to a virus comprising a genome that includes a mutation encoding a substitution of amino acid 456 of the L protein by another amino acid. However, the Examiner contends that because the specification only describes a mutation where the amino acid at position 456 of PIV3 is changed to leucine, and the claims encompass a substitution of any of the 20 amino acids, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides. Applicants strongly disagree.

Recently, the Federal Circuit stated that a sequence need not appear in a patent specification to support a DNA-based invention provided that the state of the scientific knowledge at the time the application was filed includes such structural information. *Capon et al. v. Eshhar et al. v. Dudas*, Nos. 03-1480 and -1481 (Fed. Cir. Aug. 12, 2005)

In the instant case, a skilled artisan would be fully aware of the structure of the genus of polypeptides claimed. The skilled artisan would merely have to replace the nucleotide sequence encoding an amino acid at the specified location recited in the claims with any of the well-known nucleotide sequences that encode the desired amino acid. Therefore, independent claims 67 and 83, and their dependents thereon comply with the

written description requirement. Applicants respectfully request the instant rejection be withdrawn.

Claims 62, 77-80 and 84-85 also stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

The Examiner alleges that the subject matter of these claims does not appear to be supported by the specification as filed, in particular to the recitation of an insert length of 995 nucleotides. Applicants have amended these claims to recite 996 nucleotides for the minimum insert length. Support for this amendment is found in Table 10 on page 108. Therefore, amended claims 62, 77-80 and 84-85 comply with the written description requirement. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Claim Rejections – 35 USC §102

Claims 53-57, 59-66, 69-73, 75, 81, 82 and 85 stand rejected under 35 USC §102(e) as assertedly being anticipated by US Patent No. 5,869,036 to Belshe et al. ("Belshe"). Applicants respectfully traverse.

Belshe discloses the HPIV cp45 genome in schematic form and in a limited fashion discloses hybrids thereof. Belshe's hybrid genomes are derived by replacing the regions encoding the F and HN proteins of cp45 with cDNA copies of corresponding genes of a "target" virus. (See Col 9, lines 54-59 and Col. 10 lines 19-22).

In contrast, independent claims 54, 56, 70 and 72 are drawn to a PIV virus with a heterologous open reading frame or antigenic determinant from HN and/or F proteins inserted into one or more sites of a background genome or antigenome. These sites include 1) a site between the P and M open reading frames, b) a site between the N and P open reading frames, and c) a site between the HN and L open reading frames. The

Examiner states that because "one would expect that a *substitution* of a HPIV2 HN gene for the background HPIV3 would occur between the HN and L open reading frames", Belshe anticipates these claims (emphasis added).

The Examiner should consider first that when a substitution occurs, the heterologous segment replaces the segment normally present at the same location. That is, not between two open reading frames as recited in the claims (the recited ORFs are in adjacent genes), but within or encompassing the ORF. For example, substitution of the HN gene does not result in insertion of the heterologous segment between the HN and L ORFs, but rather in replacement of the entire HN gene, including the gene start sequences, the gene end sequences and the entire HN ORF.

Furthermore, Belshe does not disclose the alternative of a hybrid cp45 genome encoding an additional HN gene inserted between the HN and L open reading frames in a background PIV. Instead Belshe only discloses replacing or substituting one HN gene for another. Therefore, independent claims 54, 56, 70, 72 and their dependents thereon are not anticipated by Belshe. Applicants respectfully request that the standing rejection of these claims be reconsidered and withdrawn.

Independent claims 53 and 69 recite a PIV background genome or antigenome comprising a polynucleotide encoding a wild-type L protein. Because Belshe clearly does not disclose a hybrid genome encoding a wild-type L protein, Belshe cannot anticipate claims 53 and 59. Although the Examiner states that "Belshe's construct is a cp45 genome with a wild type L gene introduced", (page 5 of the office action), it is clear that the cp45 genome does not have the wild-type gene introduced into it. The wild type L gene is in its own plasmid construct. Resulting viruses package a genome that is a cp45 viral genome, including all of the mutations shown in FIG. 1 of the Belshe reference. (See Example 5 in Belshe and Applicants' Exhibit 1 previously filed, which illustrates the experiments in Example 5 of Belshe). Therefore, independent claims 53 and 69, and their dependents thereon, are not anticipated by Belshe.

For the above reasons, Applicants respectfully request that the 102(e) rejection of claims 53-57, 59-66, 69-73, 75, 81, 82 and 85 be withdrawn.

Claim Rejections – 35 USC §103

The Examiner has rejected claims 58, 64, 74 and 84 under 35 USC §103(a) as allegedly obvious over Belshe. Applicants respectfully traverse.

The above referenced claims are dependent on independent claims 56, 62, 69, 70 and 72. For the reasons explained above, these independent claims are allowable over Belshe. Therefore, claims 58, 64, 74 and 84 are also free of this rejection at least by virtue of their dependency from a claim free of the cited prior art. Applicants respectfully request that the instant rejection be reconsidered and withdrawn.

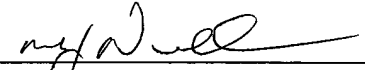## Rejection under non-statutory double-patenting

The Examiner presents a number of provisional obviousness-type double patenting rejections. Applicants request that these issues should be held in abeyance since prosecution is continuing in both cases and the issue may be resolved by amendments in the various applications. See MPEP 804. If necessary, Applicants will file a Terminal Disclaimer following the procedure outlined in the above-mentioned section of the MPEP.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested. Should the Examiner contemplate issuance of an Office Action other than a Notice of Allowance, she is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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